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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,381	03/17/2004	Jean D.A. Carruthers	D3127 RE	2839

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,381	CARRUTHERS ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040317*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Maintenance fees are not yet due for U.S. Patent No. 6,358,917, and therefore the reissue procedures are available for this patent.

2. The consent of assignee to the reissue and the offer to surrender have been received.

The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

3. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,583,114 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

4. Claims 1-30 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows: Claims 5-11, 13, 14, and 23-25 contain new matter because they recite administering Botulinum toxin, and do not specifically require that the Botulinum toxin be injected. The original disclosure of the invention is limited to injection of the Botulinum toxin (see, e.g., column 2, lines 30, 46, and 49; column 3, lines 31-48 and 62; column 4, lines 1-3, 28-31; and the originally-filed claims) and does not disclose administration in general. More general administration methods embraced by the current claim language would include topical

and mucosal delivery, which are not contemplated by the original disclosure of the invention. Claims 5-11, 13, and 14 contains new matter as they recite administering Botulinum toxin to a region in proximity to each of the corners of a mouth, and do not require that the Botulinum toxin be injected to the depressor anguli oris. The original disclosure of the invention for treating downturn of corners of a patient's mouth is limited to injection into the depressor anguli oris (see, e.g., column 2, lines 29-31, 46, and 49-55; column 4, lines 1-3, 28-37; and the originally-filed claims) and does not disclose other areas in proximity of the mouth. Claim 11 contains new matter to the extent that the range for the amount of Botulinum toxin extends below about 2 units. The original disclosure at column 4, lines 37-41, discloses a lower limit of 2(±10%) and does not indicate that lower amounts could also be effective. Claims 15-22 and 26 contain new matter because they recite treating severe upper lip wrinkles without also requiring that this treatment be in conjunction with treatment of Marionette lines and sad mouth by injection of Botulinum toxin into the depressor anguli oris. The original disclosure at column 4, lines 5-7, discloses treating severe upper lip wrinkles only "in conjunction with this invention". Claims 15-20 and 22-26 contain new matter because they recite treating severe upper lip wrinkles, but are not limited to the injection of any particular amounts of Botulinum toxin. The original disclosure at column 4, lines 8-11, is limited to injecting a total dose in the order of 4 Units for the entire upper lip. Claims 23-25 and 27-30 contain new matter because they do not require that the Botulinum toxin be injected into both depressor anguli oris muscles (i.e. bilateral injection), but rather embrace injection into only one of the two depressor anguli oris muscles. The original disclosure of the invention is limited to bilateral injection when injecting into the depressor anguli oris (see, e.g., column 2, lines 29-31 and 46-55; column 4, lines 22-24; and the

originally filed claims). Claim 30 contains new matter because it recites further injection at any site located above a patient's mouth, whereas the original disclosure is limited to further injection of about 4 Units into the orbicularis oris (see, e.g., column 4, lines 5-11). Also, the limitation "a site located above the patient's mouth" does not even require that the further injection be into the lip area. Unlimited injections anywhere above the mouth are not contemplated by the original disclosure. Applicants have not indicated where the original disclosure of the invention supports the new claim language.

5. Claims 5-11 and 13-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. To the extent that the claims contain new matter under 35 U.S.C. 251, they also lack written description in the original disclosure under 35 U.S.C. 112, first paragraph. See the above rejection under 35 U.S.C. 251 set forth in section 4.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

7. Claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by the Bikhazi et al article (Otol. Head Neck Surg., Vol. 117, pages 303-307). The Bikhazi et al article teaches improving facial symmetry by injecting botulinum toxin A into the depressor anguli oris muscle. See, e.g., the Abstract; Table 2; and page 304, paragraph bridging columns 1 and 2. Injection of botulinum toxin A into the depressor anguli oris muscle will inherently result in alleviating downturn of the corner of the mouth where the muscle is located.

8. Claims 15-22 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by the Carruthers article (57th Annual Meeting American Academy of Dermatology, pages 21-22) in view of the Klein article (57th Annual Meeting American Academy of Dermatology, pages 20-20c). The Carruthers article teaches injecting 4 units per lip of BOTOX, i.e. botulinum toxin,

into the orbicularis oris muscle in order to treat dramatic vertical lip lines, i.e. severe upper lip wrinkles. This treatment is followed by laser resurfacing. See page 21, section 2. The Klein article teaches that BOTOX is Botulinum toxin type A. See page 20, last paragraph.

The declaration under 37 CFR 1.132 by Carruthers et al filed June 11, 2001 during prosecution of parent application 09/382,002 is insufficient to show that the reference is not "by another" and therefor unavailable as prior art under 35 U.S.C. 102(a). This is because this rejection relies upon a completely different section of the Carruthers article, and the declaration does not state that the description at page 21, section 2, of the Carruthers article originated from the joint work and invention of the instant inventors.

9. Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being obvious over the Sabbaugh article (Eye World, Vol. 3, pages 37-38). The Sabbaugh article teaches injecting small amounts of botulinum toxin A around the vermillion line in order to reduce orbicularis oris function and reduce perioral rhytids, i.e. lip wrinkles. See, e.g., page 37, column 2, second full paragraph.

10. Claims 17-21 are rejected under 35 U.S.C. 103(a) as being obvious over the Sabbaugh article (Eye World, Vol. 3, pages 37-38). Application of the Sabbaugh article is the same as in the above rejection of claims 15 and 16. The Sabbaugh article teaches injection of small amounts of botulinum toxin A, but does not teach Applicants' particularly claimed ranges. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal amounts for the botulinum toxin A of the Sabbaugh article because dosage is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

11. The reference cited on the attached Notice of References Cited (PTO-892) was cited and considered during prosecution of parent application 09/382,002.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

August 31, 2004